

and physiologically acceptable salts thereof, wherein:

X is a [member selected from the group consisting of a] hydrophobic aliphatic hydrocarbon chain containing from about 4 to about 30 carbon atoms and having one or more nonconjugated cis double bonds in the middle portion of the chain;

Y is selected from the group consisting of amide and ester radicals; and

Z is selected from the group consisting of hydrogen, lower alkyl, hydroxy substituted lower alkyl, aryl, hydroxy substituted aryl, heterocyclic and hydroxy substituted heterocyclic radicals;

wherein if X contains from [19 to 22] 18 to 21 carbon atoms, Z cannot be hydrogen if Y is an amide radical.

19. (amended) The formulation of claim 12 wherein Z includes an [alkyl] alkyl group alpha to the amido nitrogen.

#### REMARKS

No claims have been cancelled. Claims 1, 8, 10, 12 and 19 have been amended. Claims 1-22 are pending in this application.

The amendment is supported by the disclosure. In particular, the hydroxy substituted aryl moiety recited in the Z group of claim 12 was inadvertently not listed in the previous amendment to claim 12. The present amendment adding hydroxy substituted aryl to the Z group of claim 12 is supported by claim 12 as originally filed. The amendment to the preamble of claim 12 is supported by claim 12 as filed. The amendment to claims 8 and 19 corrects a typographic error.

#### **THE 35 U.S.C. SECTION 102(b) REJECTION OF CLAIMS 1, 3, 5-6, 10, 12, 14 and 16-17 OVER NELSON ('827):**

Claims 1, 3, 5-6, 10, 12, 14 and 16-17 were rejected under 35 U.S.C. section 102(b) as allegedly being anticipated by U.S. Patent No. 4,497,827 to Nelson et al.

- **The Nelson reference does not anticipate each and every element of claims 12, 14 and 16-17 directed to a pharmacological formulation.**

"It is axiomatic that for prior art to anticipate under §102 it has to meet every element of the claimed invention." Stoller v. Ford Motor Co., 18 USPQ2d 1545, 1547 (Fed. Cir. 1991).

Applicants' claims 12-20 and 22 are directed to a pharmacological formulation comprising a compound having a recited structure. The Nelson reference only appears to anticipate Applicants' claim 12 when X contains from 18 to 21 carbon atoms; Z is hydrogen; and Y is amide. Claim 12 has been amended to exclude the above overlap so that the Nelson reference does not anticipate each and every feature of amended claim 12. Amended claim 12, and claims depending therefrom, are not anticipated by the Nelson reference for at least this reason.

- **The Nelson reference does not anticipate each and every element of claims 1, 3, 5-6 and 10 drawn to a method.**

Applicants' claims 1-11 and 21 are directed to specified methods including, *inter alia*, the use of a chemical compound having a recited structure to inhibit transport of anandamide in an individual or animal.

The Nelson reference only appears to anticipate Applicants' claim 1 when X contains from 18 to 21 carbon atoms; Z is hydrogen; and Y is amide. Claim 1 has been amended to exclude the above overlap so that the Nelson reference does not anticipate each and every feature of amended claim 1. Amended claims 1 and 10, and claims depending therefrom, are not anticipated by the Nelson reference for at least this reason.

- **The Nelson reference can not make obvious each and every element of claims 1, 3, 5-6 and 10 drawn to a method.**

- **The Office Action admits that the features of claims 1, 3, 5-6, 10, 12, 14 and 16-17 are not explicitly anticipated by the Nelson reference.**

When the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears in the reference. In re Yates, 211 USPQ 1149, 1151 (CCPA 1981). The Office Action has not indicated where the Nelson reference teaches that administration of Applicants' recited compounds

would inhibit anandamide transport.

The Office Action only asserts that “[I]t is inherent that said administration of arachidonamide would inhibit anandamide transport.” Thus, the Office Action admits that there is no explicit teaching or suggestion of Applicants’ claimed invention in the Nelson reference and that the rejection of claims 1, 3, 5-6, 10, 12, 14 and 16-17 is based only on an allegedly inherent property.

- **The burden is on the Office to provide a basis in fact and/or technical reasoning to establish with certainty that an asserted property is inherently present in the prior art.**

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. §§102 or 103. See MPEP §2112. However, “[t]he doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation. Probabilities are not sufficient . . . A prior inherent event cannot be established based upon speculation or where a doubt exists.” Ethyl Molded Products Co. v. Betts Package Inc., 9 USPQ2d 1001, 1032-1033 (E.D. Ky. 1988). The Court of Appeals for the Federal Circuit has reinforced this position stating: “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To rely on the theory of inherency in rejecting a claim under 35 U.S.C. §§102 or 103, “. . . the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied art.” Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). “Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in the references.” Phillips Petroleum Co. v. U.S. Steel Corp., 6 USPQ2d 1065, 1076-1077 n12 (D. Del. 1987), *aff’d* 9 USPQ2d 1461 (Fed. Cir. 1989).

Further, the chemical arts are known to be unpredictable so that a person of ordinary skill is cautious about extrapolating from teachings within those arts. See, for

example, In re Marzocchi, 169 USPQ 367, 368-370 (CCPA 1971), acknowledging the unpredictability within the chemical arts. This caution in extrapolating from chemical teachings is especially true when, as in the present case, the Nelson reference teaches a biochemical mechanism that is different from the mechanism disclosed in the pending application. In such a case, a person of ordinary skill in the art understands that the teachings are uncertain and the different mechanisms may not be related.

Applicants' claims 1, 3, 5-6 and 10 can not be obvious over the Nelson reference.

In sum, all of the present rejections have been fully considered. The pending claims are novel and non-obvious in view of the cited references. Accordingly, it is believed that the application now stands in condition for allowance and prompt, favorable action thereon as earnestly solicited.

Respectfully submitted,

Alexandros MAKRIYANNIS et al

By 

James E. Piotrowski  
Registration No. 43,860  
Alix, Yale & Ristas, LLP  
Attorney for Applicant

Date: 1/24/2003  
750 Main Street  
Hartford, CT 06103-2721  
(860) 527-9211